MAY 2 8 2014

SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K_____

GENERAL INFORMATION

Applicant:

St. Jude Medical, Inc.
645 Almanor Avenue
Sunnyvale, CA 94085
USA
Phone: (408) 738-4883
Fax: (408) 735-8750

Contact Person:

Michael McSweeney
Regulatory Affairs
St. Jude Medical, Inc.
645 Almanor Avenue
Sunnyvale, CA 94085
USA
Phone: (408) 522-6112
Fax: (818) 256-8795
Email: mmcsweeney@sjm.com

Date Prepared: November 13, 2013

DEVICE INFORMATION

Trade Name:

SJM Confirm™ Implantable Cardiac Monitor (ICM), Model DM2102

Generic/Common Name:

Cardiovascular Monitoring Device

Classification:

21 CFR §870.2800, Medical magnetic tape recorder, Class II
21 CFR §870.2920, Telephone electrocardiograph transmitter and receiver, Class II

Product Code:

MXC

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICE(S)

- St. Jude Medical, Inc. SJM Confirm (DM2100) ICM (K122161)
- St. Jude Medical, Inc. SJM Confirm (DM2100) ICM (K122090)
- Medtronic, Inc. Reveal XT Insertable Cardiac Monitor (K082475)
- St. Jude Medical, Inc. SJM Confirm (DM2100) ICM (K081365)

INDICATIONS FOR USE

The SJM Confirm™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias.

The SJM Confirm ICM, Model DM2102, is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

PRODUCT DESCRIPTION

The SJM Confirm ICM is a cardiovascular monitoring device used to record and play back physiological signals.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the SJM Confirm ICM are similar to the predicate devices. Performance data were provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The SJM Confirm ICM is substantially equivalent to the SJM Confirm (DM2100) ICM (K122161), the SJM Confirm (DM2100) ICM (K122090), the Medtronic, Inc. Reveal XT Insertable Cardiac Monitor (K082475), and the SJM Confirm (DM2100) ICM (K081365). The subject and the predicate devices are cardiovascular monitoring devices used to record and play back physiological signals. The indications for use for the SJM Confirm ICM are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the SJM Confirm ICM is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary nonclinical and clinical testing was conducted on the SJM Confirm ICM to support a determination of substantial equivalence to the predicate devices, including:

- Software Verification and System Validation
- Clinical Study

There are no changes to the hardware, firmware, materials, manufacturing processes, sterilization, shelf life, or packaging of the SJM Confirm (DM2102) ICM as compared to the cleared SJM Confirm (DM2100) ICM included in this submission. Therefore, biocompatibility, sterilization, shelf life, packaging, electromagnetic compatibility (EMC), electrical safety, mechanical performance, firmware, component, and usability testing was not repeated since clearance of K122161, K122090, and K081365.

SECTION 5
510(k) SUMMARY (CONT.)

Software testing, system validation testing, and clinical performance testing were performed to demonstrate the SJM Confirm ICM meets the required performance criteria to support a determination of substantial equivalence to the predicate devices.

The results of testing show that the SJM Confirm ICM performs as intended and is safe for its intended use.

CONCLUSION

The SJM Confirm ICM is an implantable cardiovascular monitoring device and shares its design and mechanism of action with the identified predicate devices. The results of nonclinical and clinical testing demonstrate that the SJM Confirm ICM functions to its specifications, performs as intended, and exhibits the appropriate characteristics of an implantable cardiovascular monitoring device. The SJM Confirm ICM is substantially equivalent to the predicate devices in terms of technological characteristics, intended use, and performance. No new issues of safety or effectiveness are raised by the SJM Confirm ICM.

SUMMARY

The SJM Confirm ICM is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66 G609
Silver Spring, MD 20993-0002

May 28, 2014

St. Jude Medical, Inc.
Michael Mc Sweeney
645 Almanor Avenue
Sunnyvale, CA 94085 US

Re: K133481
Trade/Device Name: SJM Confirm Implantable Cardiac Monitor (ICM, Model DM2102)
Regulation Number: 21 CFR 870.2800
Regulation Name: Implantable Cardiac Monitor
Regulatory Class: Class II
Product Code: MXC
Dated: May 5, 2014
Received: May 2, 2014

Dear Michael Mc Sweeney,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

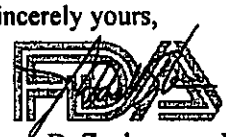
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Brain D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133481

Device Name: SJM Confirm Implantable Cardiac Monitor (ICM), Model DM2102

Indications For Use:

The SJM Confirm™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias.

The SJM Confirm ICM, Model DM2102, is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.05.28 17:42:42 -04'00'